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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,507	06/19/2000	Horst Peschel	4070-174US (K400417US)	3984

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/21/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/596,507

Applicant(s)
Gummersbach

Examiner
Robert C. Hayes, Ph.D.

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 8, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-49, 51-54, 58-61, 63, 64, 66-79, 83, and 84 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-49, 51-54, 58-61, 63, 64, 66-79, 83, and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/03 has been entered.

2. Claim 52 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form, for the reasons made of record in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03) and as follows.

In contrast to Applicant's assertions on page 9 of the response, base claim 44 is directed to "a synthetic neuronal tissue *derived from a brain or spinal cord*" [emphasis added], which intrinsically comprises many different types of cells, and therefore, is not reasonably "derived from a single cell" as now claimed in dependent claim 52. In other words, amended claim 52 is little different from that previously claimed (i.e., "derived from a monoclonal cell line"), and still does not limit base claim 52, as previously made of record.

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3. Claims 44-49, 51-54, 58-61, 63-64, 66-79 & 83-84 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record for cancelled claims 26-43 in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03), and as follows.

In contrast to Applicant's assertions on pages 9-13 of the response, no proper basis exists for any of these different concepts, for the reasons previously made of record in Paper No: 12 (mailed 11/05/02). In other words, mix and matching different concepts within the specification still constitute new matter. Moreover, although Applicants are permitted to be their own lexicographer (e.g., as it relates to the term "synthetic neuronal tissue"), no term may be given meaning repugnant to the usual meaning of the term (see MPEP 608.01 (o)); especially when the specification fails to specifically describe or define such. Lastly, the recitation of "synthetic tissue does not comprise sufficient glial cells to provoke an immune response" is not the same as "these cultures do not include cells that give rise to immunogenic glial cells in large enough quantities to induce any detectable immune response" [emphasis added], in contrast to Applicant's assertions. Nor is the recitation of "*less than 90/95% of the cells in the synthetic tissue are the progenitor cells*" the same as "*the percentage of such specific neurons in the tissue samples should be greater than 90%, preferably greater than 95%*" [emphasis added]. Thus, Applicants' arguments are not persuasive.

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4. Claims 44-49, 51-54, 58-61, 63-64, 66-79 & 83-84 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03), and as follows.

In contrast to Applicant's assertions on pages 13-15 of the response, no where in Paper No: 12 did the Examiner argue the phrases recited at the bottom of page 13 and the top of page 14; thereby, making Applicant's comments moot regarding this point. Second, because the specification fails to define the metes and bounds that the term "differentiating-promoting factors" encompasses, in which no universal differentiating-promoting factor exists nor would all cells encompassed by the claims reasonably express receptors to all such putative factors (if known), Applicant's arguments remain not persuasive.

5. Claims 44-49, 51-54, 58-61, 63-64, 66-79 & 83-84 stand rejected under 35 U.S.C. 102(b) as being anticipated by Boss et al. (US Patent 5,411,883; IDS Ref #3), for the reasons made of record in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03), and as follows.

In contrast to Applicant's assertions on pages 15-17 of the response, no purity limitations, etc. are recited in the claims to distinguish that claimed from that taught by Boss et al., in which the claims further recite open claim language. Therefore, Applicant's arguments are not persuasive for the reasons made of record, which is further consistent with that held by the courts in *Ex parte Gray*, *In re Best*, *In re Thorpe* and *In re Marosi*, previously made of record.

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6. Claims 44-49, 51-54, 58-61, 63-64, 66-79 & 83-84 stand rejected under 35 U.S.C. 102(b) as being anticipated by Emory University/Luskin et al. (WO 97/02049; IDS Ref #10), for the reasons made of record in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03), and as follows.

In contrast to Applicant's assertions on page 17 of the response, no purity limitations, etc. are recited in the claims to distinguish that claimed from that taught by Luskin et al., in which the claims further recite open claim language. Therefore, Applicant's arguments are not persuasive for the reasons made of record, which is further consistent with that held by the courts in *Ex parte Gray*, *In re Best*, *In re Thorpe* and *In re Marosi*, previously made of record.

7. This is a RCE of applicant's earlier Application No. 09/596507. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
July 16, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600